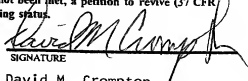


FORM PTO-1500 (REV. 9-2001)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER 1001.1591101	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371					
INTERNATIONAL APPLICATION NO. PCT/EP00/07739		INTERNATIONAL FILING DATE 9 August 2000		U.S. APPLICATION NO. (if known, see 37 CFR 1.5 10/070939	
TITLE OF INVENTION GUIDING AID		PRIORITY DATE CLAIMED 9 September 1999			
APPLICANT(S) FOR DO/EO/US Michael Schwager					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input checked="" type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input checked="" type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input type="checkbox"/> Other items or information:</p>					
<p><small>CERTIFICATE UNDER 37 CFR 1.106: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited at the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of 6135513004145, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20531 on the 7th day of March, 2002.</small></p> <p><i>Kathleen L. Bodley</i> Kathleen L. Bodley</p>					

U.S. APPLICATION NO. (if known) 107070939		INTERNATIONAL APPLICATION NO. PCT/EP00/07739		ATTORNEY'S DOCKET NUMBER 1001.1591101	
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1040.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT = \$ 890.00				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	15 - 20 =	0	x \$18.00	\$	
Independent claims	1 - 3 =	0	x \$84.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$280.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,020.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				+	
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492(f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30				\$	
TOTAL NATIONAL FEE =				\$1,020.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$1,020.00	
				Amount to be refunded: \$	
				charged: \$	
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>1020.00</u> to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0413</u> . A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
David M. Crompton CROMPTON, SEAGER & TUFTE, LLC 331 Second Avenue South, Suite 895 Minneapolis, MN 55401-2246					
				 SIGNATURE David M. Crompton NAME 36,772 REGISTRATION NUMBER	

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michael Schwager

Serial No.: Unknown

Examiner: Unknown

Filed: March 7, 2002

Group Art Unit: Unknown

For: GUIDING AID

Docket No.: 1001.1591101

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of E1 855120061 US, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C., 20231 on this 7th day of March, 2002.

By

Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Please amend the above-captioned patent application as follows:

In the Specification

In the Specification at page 9, beginning at line 2, please insert the following paragraph:

-- A guiding aid for an instrument to be advanced within a vascular system, particularly the human vascular system, comprising a flexible shapeable shaft comprising a first bent section having a first curvature (K_1) and at least one further bent section, wherein said bent sections of said shaft have the same sign of curvature and are located substantially within the same plane. Such a guiding aid may be pre-formed by the manufacturer such that the guiding aid may be

introduced into vascular branchings both from large lumen and small lumen vessels by a physician manipulating the instrument from its proximal end. --

In the Specification at page 1 beginning at line 2, please insert the following heading:

-- Field of the Invention -- .

In the Specification at page 1 beginning at line 5, please insert the following heading:

-- Background of the Invention -- .

In the Specification at page 2 beginning at line 17, please insert the following heading:

-- Summary of the Invention -- .

In the Specification at page 4 beginning at line 10, please insert the following heading:

-- Brief Description of the Drawings -- .

In the Specification at page 4 beginning at line 23, please insert the following heading:

-- Detailed Description of the Invention -- .

In the Claims

Please cancel claims 16-18, and amend claims 1-15 as follows:

1. (Once Amended) A guiding aid for an instrument to be advanced within a vascular system comprising a flexible shapeable shaft including a first bent section having a first

curvature K_1 , and at least one further bent section, with said bent sections of said shaft having the same sign of curvature and being located substantially in the same plane.

2. (Once Amended) The guiding aid of claim 1, wherein the shaft comprises a single further or second bent section having a second curvature K_2 , which second bent section is located proximal to the first bent section.

3. (Once Amended) The guiding aid of claim 2, wherein the radius of the first curvature K_1 of said first bent section is smaller than the radius of the second curvature K_2 of said second bent section.

4. (Once Amended) The guiding aid of claim 3, further comprising a straight intermediate section between said first bent section and said second bent section.

5. (Once Amended) The guiding aid of claim 4, further comprising a straight end section distal to the first bent section.

6. (Once Amended) The guiding aid of claim 5, wherein the straight end section and the straight intermediate section include a first obtuse angle (α_1).

7. (Once Amended) The guiding aid of claim 6, wherein said straight intermediate section along the axis of the guiding aid includes a second obtuse angle (α_2).

8. (Once Amended) The guiding aid of claim 7, wherein said first obtuse angle (α_1) and second obtuse angle (α_2) are between 120° and 150°.

9. (Once Amended) The guiding aid of claim 1, wherein said bent sections are substantially in the shaped of a circular arc.

10. (Once Amended) The guiding aid of claim 1, wherein said shaft is tapered toward its distal end.

11. (Once Amended) The guiding aid of claim 1, wherein a helically wound spring is located around at least a part of said shaft.

12. (Once Amended) The guiding aid of claim 11, wherein said helically wound spring is provided at its distal end with a rounded terminal element.

13. (Once Amended) The guiding aid of claim 1, wherein said shaft is made of a material having superelastic characteristics.

14. (Once Amended) The guiding aid of claim 13, wherein said shaft is made of superelastic nitinol.

15. (Once Amended) The guiding aid of claim 1, wherein radiopaque means are provided in the region of said distal end of said shaft.

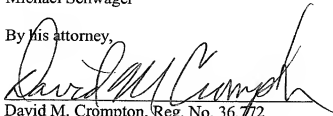
REMARKS

Applicants request that this Preliminary Amendment be made of record and fully considered prior to the first office action on the merits. Upon entry of this Amendment, claims 12-23, 25-43 and 45-48 are pending. Any inquiry regarding this matter may be directed to the undersigned representative at (612) 677-9050.

Respectfully submitted,

Michael Schwager

By his attorney,



David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
331 Second Avenue South, Suite 895
Minneapolis, Minnesota 55401-2246
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

Date: 3/7/02

Serial No. Unknown

Version with Markings to Show Changes Made

In the Specification:

Paragraph beginning at line 2 of page 9 has been amended as follows:

A guiding aid for an instrument to be advanced within a vascular system, particularly the human vascular system, comprising a flexible shapeable shaft [(2)] comprising a first bent section [(4)] having a first curvature (K_1) and at least one further bent section [(6)], wherein said bent sections [(4, 6)] of said shaft [(2)] have the same sign of curvature and are located substantially within the same plane [plain (E)]. Such a guiding aid may be pre-formed by the manufacturer such that the guiding aid may be introduced into vascular branchings both from large lumen and small lumen vessels by a physician manipulating the instrument from its proximal end. [Fig 4]

Paragraph beginning at line 2 of page 1, has been amended as follows:

-- Field of the Invention -- .

Paragraph beginning at line 5 of page 1, has been amended as follows:

-- Background of the Invention -- .

Paragraph beginning at line 17 of page 2, has been amended as follows:

-- Summary of the Invention -- .

Paragraph beginning at line 10 of page 4, has been amended as follows:

-- Brief Description of the Drawings -- .

Paragraph beginning at line 22 of page 4, has been amended as follows:

-- Detailed Description of the Invention -- .

In the Claims:

Claims 16, 17 and 18 have been cancelled.

Claims 1-15 have been amended as follows:

1. (Once Amended) A g[G]uiding aid for an instrument to be advanced within a vascular system comprising a flexible shapeable shaft [(2) comprising] including a first bent section [(4)] having a first curvature K_1 , [characterized by shaft (2) comprises] and at least one further bent section [(6)], with said bent sections [(4, 6)] of said shaft [(2)] having the same sign of curvature and being located substantially in the same plane [plain (E)].

2. (Once Amended) The g[G]uiding aid [as claimed in] of claim 1, [characterized in that said] wherein the shaft [(2)] comprises a single further or second bent section [(6)] having a second curvature K_2 , which second bent section is located proximal to the first bent section [(4)].
3. (Once Amended) The g[G]uiding aid [as claimed in] of claim 2, [characterized in that] wherein the radius of the first curvature K_1 of said first bent section [(4)] is smaller than the radius of the second curvature K_2 of said second bent section [(6)].
4. (Once Amended) The g[G]uiding aid [as claimed in anyone of claims 2 or] of claim 3, [characterized in that said shaft (2) comprises] further comprising a straight intermediate section [(8)] between said first bent section [(4)] and said second bent section [(6)].
5. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims, characterized in that said shaft (2) comprises] of claim 4, further comprising a straight end section [(10)] distal to the first bent section [(4)].
6. (Once Amended) The g[G]uiding aid [as claimed in claims 4 and] of claim 5, [characterized in that] wherein the straight end section [(10)] and the straight intermediate section [(8)] include a first obtuse angle (α_1).
7. (Once Amended) The g[G]uiding aid [as claimed in claim 4 or in claims 4 and 5 or in] of claim 6, [characterized in that] wherein said straight intermediate section [(8) and] along the axis [(12)] of the [instrument] guiding aid includes a second obtuse angle (α_2).
8. (Once Amended) The g[G]uiding aid [as claimed in] of claim [6 or] 7, [characterized in that] wherein said first obtuse angle (α_1) and/or second obtuse angle (α_2) are between 120° and 150° [and preferably are about 135°].
9. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims, characterized in that] of claim 1, wherein said bent sections [(4, 6)] are substantially in the shaped of a circular arc.
10. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims, characterized in that] of claim 1, wherein said shaft [(2)] is tapered toward[s] its distal end [(14)].
11. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims, characterized in that] of claim 1, wherein a helically wound spring [(16, 20)] is located around at least a part of said shaft [(2)].
12. (Once Amended) The g[G]uiding aid [as claimed in] of claim 11, [characterized in that] wherein said helically wound spring [(20)] is provided at its distal end with a rounded terminal element [(18)].

13. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims, characterized in that] of claim 1, wherein said shaft [(2)] is made of a material having superelastic characteristics.

14. (Once Amended) The g[G]uiding aid [as claimed in] of claim 13, [characterized in that] wherein said shaft [(2)] is made of superelastic nitinol.

15. (Once Amended) The g[G]uiding aid [as claimed in anyone of the preceding claims] of claim 1, [characterized in that] wherein radiopaque means [(20)] are provided in the region of said distal end [(14)] of said shaft [(2)].

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Guiding Aid

The invention relates to a guiding aid for an instrument to be advanced within a vascular system, particularly the human-vascular system, comprising a flexible, formable shaft having a bent section with a predetermined curvature.

5 Such guiding aids are used in transluminal interventions in the human vascular system where elongated instruments such as guide wires or catheters are manipulated at their proximal end by a physician to advance those instruments along a certain path through the vascular system to a site of treatment. For this purpose the instrument comprises at its distal end a tip which has approximately J-shape and which either is pre-formed by the manufacturer or is
10 individually bent by the physician. The column strength and the torsional strength of the instrument provide for axial and rotational movements being transferred from the proximal end of the instrument directly to the tip thereof. With the distal J-bow being correctly dimensioned the physician may navigate the instrument along a path selected by him through a branched vascular system such as the human blood vessel system.

15 From the prior art there are known various embodiments of instruments with such guiding aids. US-A-4 846 186 discloses a flexible guide wire for advancing diagnostic and therapeutical catheters. The tapered core wire is flattened at its distal end such that it may be bent by the treating physician in this area into J-shape. A further application is shown in European Patent 0 220 285 wherein a balloon catheter is provided with a fixedly installed
20 guide wire. The shaft of the wire which protrudes beyond the balloon is tapered and is surrounded by a wire helix. In the distal end section there is attached to the wire a shaped element made of stainless steel which in the relaxed state has a pre-selected curvature to serve as guiding aid. A guiding aid of the type mentioned above further is known from WO 97/32518; here there is provided a guide wire having a pressure measurement feature. At the
25 distal end of the tubular wire there are located lateral openings through which a pressure pulse of the blood may propagate through the lumen of the tubular element to a pressure sensor located at the proximal end. A tip made of a formable shaft and a wire helix surrounding the shaft are provided at the distal end of the tubular element. Once the tips of the aforementioned embodiments are pre-formed the shape of the tip may not be changed any further during use
30 thereof.

A guide wire having a tip the shape of which may be changed is known from US-A-5 040 543. For this purpose the wire comprises an axially moveable core element the distal end of which may straighten the pre-curved helical wire tip. Thus the physician may control the size of the J-bow during the treatment from outside the patient. However, this construction is complicated and there is the risk, that the tip of the moveable core element may emerge between adjacent windings of the wire helix and may injure the inner wall of the vessel.

US-A-4 925 445 discloses a guide wire for a catheter having a comparably stiff main section and a comparably flexible distal end section. These sections are made at least in part of a super elastic member. In order to prevent that the tip of the distal end section penetrates the wall of the vessel the tip is R-shaped, ball-shaped, J-shaped, annular or spiral. In order to be able to insert the distal end section in a simple and safe manner to a pre-selected position within the blood vessel, the distal end section is pre-formed by a curvature that corresponds to the anatomy of the vascular system or the vascular branching. This is disadvantageous in that for each individual intervention an individual shape of the guide wire tip has to be pre-manufactured which requires extensive storage.

It is therefore an object of the invention to provide for a guiding aid of the above mentioned type that is simple in construction and safe in application and which may be used for guiding elongated instruments in branchings of both large and small vessel diameters. This object is attained by a guiding aid of the above mentioned type, the shaft of which comprises at least one further bent section, wherein all bent sections of the shaft exhibit the same sign of curvature and are located substantially in the same plain. In large vessels the shaft, by means of the plurality of sections being bent in the same direction, may provide for sufficient total curvature such that the guiding aid may be threaded into a branching, optionally by bearing against a wall of the vessel opposite the branching. When being used in small vessels the further bent sections of the shaft proximal the first bent section of the guiding aid are straightened while the distal first bent section, when the curvature thereof is suitably dimensioned, maintains its shape to be maneuvered into a branching. Thus there is provided for an industrially pre-formable and thus standardized guiding aid that is suited for being threaded into branchings both from large and from small vessels. Furthermore, the physician no longer has to pre-form the shaft prior to the intervention himself.

In a preferred embodiment of the invention the shaft comprises just one further or second bent section having a further or second curvature that is located proximal of the first bent section such that the advantages of the invention are attained in a particular simple way by requiring that only two bent sections have to be pre-formed.

In a preferred embodiment of the invention the radius of curvature of the first bent section is smaller than the radius of curvature of the second bent section. Thereby the risk for buckling of the proximal curvature is lowered and the proximal curvature thereby is better adapted to transfer an axial movement to the distal curvature and the tip.

- 5 Preferably the shaft comprises between the first bent section and the second bent section a straight intermediate section in order to provide for an intermediate section that is stable for the transfer of axial movements which for example assists in preventing the distal end section of the guiding aid from again leaving a branching already entered by the distal end section.

In an advantageous embodiment of the invention the shaft comprises a straight end section distal to the first bent section. This distal end section facilitates the entry into a branching by acting as support for the distal end of the shaft protruding into the branching.

In a preferred embodiment of the invention the straight end section and the straight intermediate section include a first obtuse angle and the straight intermediate section and the instrument axis include a second obtuse angle comprising an angle of in the range of from 120 to 150°, preferably of about 135°. As a result the straight end section is oriented laterally, for example under an angle in the order of about 90°, to the instrument axis in the direction of the opening of a branching and may be introduced into the branching particularly easy.

Advantageously the bent sections are substantially in the shape of a circular arc. This type of curvature is uniform and may be provided for with the most simple means.

- 20 In a further preferred embodiment of the invention the shaft is tapered towards its distal end, such that the shaft is more and more flexible towards its distal end. Thereby the risk of injury of the inner wall of the vessel by the tip of the shaft of the guiding aid is reduced.

- In a further preferred embodiment of the invention there is provided around the shaft at least partially a helically wound spring. Thereby the risk for kinking of the wound shaft section is lowered while maintaining high flexibility. Furthermore, by means of the spring a rapid change of the outer diameter of the guiding aid is avoided in the tapered shaft. Preferably, the helically wound spring is provided at its distal end with a rounded terminal element to further lower the risk of injury.
- 25

- In a further advantageous embodiment of the invention the shaft is comprised of a material with super elastic characteristics, preferably of super elastic Nitinol. Due to the shaft shape of the invention being adapted to be pre-shaped by the manufacturer this material having a shape memory effect may be used for the shaft.
- 30

In another preferred embodiment of the invention radiopaque means are provided in the region of the distal end of the shaft such that the instrument tip may be followed during navigation by the physician on an X-ray screen.

The invention relates further to the use of a guiding aid as described above with steerable instruments. In particular, the guiding aid of the invention may be located at the distal end for example of a guide wire, a pressure sensing wire or a balloon catheter. The practical attainment of the locating procedure or the attachment respectively of a guiding aid in or at such an instrument is known from the prior art described above such that these instruments may be provided with the inventive shape of the guiding aid and its advantageous use.

Further advantages of the guiding aid of the invention will become apparent from the description of a preferred embodiment which will be described below by reference to the attached drawings wherein:

FIG. 1 shows a guiding aid comprising a J-shaped tip having the correct dimensions for the branching conditions;

FIG. 2 illustrates a guiding aid with a J-shaped tip being dimensioned too large for the branching conditions;

FIG. 3 illustrates a guiding aid with a J-shaped tip being dimensioned too small for the branching conditions;

FIG. 4 is a schematic illustration of a guiding aid of the invention;

FIG. 5 shows the guiding aid of FIG. 4 at a branching from a large vessel;

FIG. 6 shows the guiding aid of FIG. 4 at a branching from a small vessel; and

FIG. 7 shows a guide wire comprising a guiding aid of the invention in sectional view.

A prior art guiding aid for an instrument to be advanced within the human vascular system having a flexible, shapeable shaft 2 comprising a first bent section 4 having a first curvature K_1 in J-shape is shown in FIGS. 1 to 3 in vascular branchings of different size. In FIG. 1 the curvature K_1 is dimensioned such that the distance of the distal end 14 of shaft 2 from the instrument axis 12 corresponds to about the diameter of the vessel from which the guiding aid is to be threaded into a branching. In this manner the tip of the guiding aid may protrude into the branching vessel even when the guiding aid bears proximally to the bent section 4 against the wall of the vessel opposite to the opening of the branching vessel. By rotating the instrument and thereby rotating the guiding aid about the instrument axis 12 the distal end 14 thereof is introduced into the branching easily and rapidly, provided the dimension of the bent section 4 corresponds to about the vessel diameter.

In FIG. 2 the curvature K_1 is dimensioned such that the distance of the distal end 14 from the instrument axis 12 is substantially larger than the diameter of the vessel from which the guiding aid is to be introduced into a branching. Within the small vessel the bent section 4 of the guiding aid is straightened such that the tip is directed substantially in the direction of the instrument axis 12. Therefore the tip of the guiding aid tends to pass the opening of the branching which renders the threading thereof into the branching difficult.

Threading of the guiding aid into a branching is similarly difficult in case that, as is shown in FIG. 3, the curvature K_1 is dimensioned such that the distance of the distal end 14 from the instrument axis 12 is substantially smaller than the diameter of the main vessel. Within the large lumen vessel there is no suitable lateral support for the guiding aid because when the shaft 2 bears against the wall of the vessel the distal end 14 of the guiding aid does not protrude into the vessel opening. This demonstrates to what an extent the successful advancement of an instrument with guiding aid is determined by the dimensioning of the curvature K_1 in relation to the size of the vessel diameter.

The guiding aid of the invention shown in FIG. 4 comprises a flexible shapeable shaft 2 having a first bent section 4 with a first curvature K_1 and proximal thereto a second bent section 6 with a second curvature K_2 , wherein the two bent sections 4 and 6 of the shaft 2 exhibit the same sign of curvature and are positioned substantially in the same plane which in FIG. 4 is the drawing plane. Shaft 2 comprises a straight intermediate section 8 between the bent sections 4 and 6 and a straight end section 10 distal to the first bent section 4 which end section 10 constitutes with its distal end 14 the tip of shaft 2. The straight intermediate section 8 and the axis 12 of the instrument include a first obtuse angle α_1 and the intermediate section 8 and the straight end section 10 include a second obtuse angle α_2 . Bent sections 4 and 6 are substantially in the shape of a circular arc, with the radius of curvature of the first bent section 4 being smaller than the radius of curvature of the second bent section 6.

In FIGS. 5 and 6 there is shown how the guiding aid of the invention is threaded from a large vessel and from a small vessel, respectively, into a branching. As is shown in FIG. 5 the curvatures K_1 and K_2 of the two bent sections 4 and 6, respectively, are dimensioned such that the tip 14 of the guiding aid protrudes into the opening of the branching even if the main vessel has a large lumen and even if shaft 2 bears against the wall of the main vessel opposite the opening of the branching. In case of a small lumen vessel, such as is shown in FIG. 6, although the proximal bent section 6 is straightened, the distal bent section 4 is dimensioned such that its curvature K_1 may be maintained and the tip 14 of the guiding aid may be introduced into the branching.

FIG. 7 shows a guide wire that is provided with a guiding aid of the invention. The flexible, shapeable shaft 2 of the guiding aid is constituted by the distal portion of the core wire of the guide wire, which, for coronary applications, has an outer diameter of typically about 0.35 mm. A first bent section 4 has a first curvature K_1 , and proximal thereto a second bent section 6 has a second curvature K_2 , with the two bent sections 4 and 6 being bent in the same direction with respect to the axis 12 of the instrument, i.e. with the same sign of curvature, and which are positioned substantially in the same plain E, which in FIG. 7 is the drawing plain. Between the bent sections 4 and 6 shaft 2 comprises a straight intermediate section 8 having a length of approximately 3 mm, and distal to the first bent section 4 shaft 2 comprises a straight end section 10 with a length of approximately 1.5 mm. The straight intermediate section 8 and the axis 12 of the instrument include a first obtuse angle α_1 , and the straight intermediate section 8 and the straight end section 10 include a second obtuse angle α_2 , with both obtuse angles having a value of about 135° . The bent sections 4 and 6 are formed substantially in the shape of a circular arc, with the radius of curvature of the first bent section 4 being about 8 mm and the radius of curvature of the second bent section 6 being about 3 mm. Shaft 2 is tapered towards its distal end 14 via a plurality of conical intermediate sections. In order to provide for a substantially constant outer diameter of the guide wire, a helical spring 16 is wound at least partially around shaft 2, preferably within the tapered shaft portion which within the region of the distal end 14 of shaft 2 is made of an radiopaque material 20 which is threadedly connected to the proximal spring 16 at an attachment side 22 and/or is brazed or welded thereto. At the distal end 14 of shaft 2 spring 20 is provided with a rounded terminal element 18, for example a solidified droplet of brazing metal. Spring 16 is attached to shaft 2 at its proximal end and preferably also at an additional location, for example by means of a brazing or solder or adhesive connection. The core wire of the guide wire and thus shaft 2 preferably are made of Nitinol.

Although an embodiment of the invention having two bent or curved sections has been described above with reference to FIGS. 4 to 7, the guiding aid may comprise three or more bent or curved sections.

Claims

1. Guiding aid for an instrument to be advanced within a vascular system comprising a flexible shapeable shaft (2) comprising a first bent section (4) having a first curvature K_1 , characterized by shaft (2) comprises at least one further bent section (6), with said bent sections (4, 6) of said shaft (2) having the same sign of curvature and being located substantially in the same plane (E).
2. Guiding aid as claimed in claim 1, characterized in that said shaft (2) comprises a single further or second bent section (6) having a second curvature K_2 , which second bent section is located proximal to the first bent section (4).
3. Guiding aid as claimed in claim 2, characterized in that the radius of the first curvature K_1 of said first bent section (4) is smaller than the radius of the second curvature K_2 of said second bent section (6).
4. Guiding aid as claimed in anyone of claims 2 or 3, characterized in that said shaft (2) comprises a straight intermediate section (8) between said first bent section (4) and said second bent section (6).
5. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) comprises a straight end section (10) distal to the first bent section (4).
6. Guiding aid as claimed in claims 4 and 5, characterized in that the straight end section (10) and the straight intermediate section (8) include a first obtuse angle (α_1).
7. Guiding aid as claimed in claim 4 or in claims 4 and 5 or in claim 6, characterized in that said straight intermediate section (8) and the axis (12) of the instrument include a second obtuse angle (α_2).
8. Guiding aid as claimed in claim 6 or 7, characterized in that said first obtuse angle (α_1) and/or said second obtuse angle (α_2) are between 120° and 150° and preferably are about 135° .
9. Guiding aid as claimed in anyone of the preceding claims, characterized in that said bent sections (4, 6) are substantially in the shape of a circular arc.
10. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) is tapered towards its distal end (14).
11. Guiding aid as claimed in anyone of the preceding claims, characterized in that a helically wound spring (16, 20) is located around at least a part of said shaft (2).

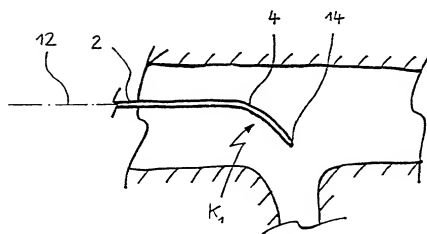
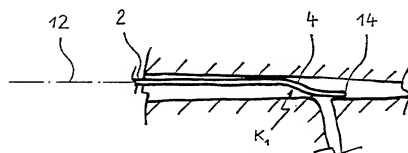
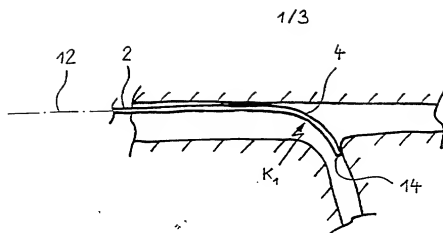
12. Guiding aid as claimed in claim 11, characterized in that said helically wound spring (20) is provided at its distal end with a rounded terminal element (18).
13. Guiding aid as claimed in anyone of the preceding claims, characterized in that said shaft (2) is made of a material having superelastic characteristics.
- 5 14. Guiding aid as claimed in claim 13, characterized in that said shaft (2) is made of superelastic nitinol.
15. Guiding aid as claimed in anyone of the preceding claims, characterized in that radiopaque means (20) are provided in the region of said distal end (14) of said shaft (2).
- 10 16. Steerable guide wire comprising a guiding aid as claimed in anyone of claims 1 to 15.
17. Steerable pressure sensing wire comprising a guiding aid as claimed in anyone of claims 1 to 15.
18. Steerable catheter, in particular steerable balloon catheter, comprising a guiding aid as claimed in anyone of claims 1 to 15.

Abstract

A guiding aid for an instrument to be advanced within a vascular system, particularly the human vascular system, comprising a flexible shapeable shaft (2) comprising a first bent section (4) having a first curvature (K_1) and at least one further bent section (6), wherein said bent sections (4, 6) of said shaft (2) have the same sign of curvature and are located substantially within the same plain (E). Such a guiding aid may be pre-formed by the manufacturer such that the guiding aid may be introduced into vascular branchings both from large lumen and small lumen vessels by a physician manipulating the instrument from its proximal end.

FIG. 4

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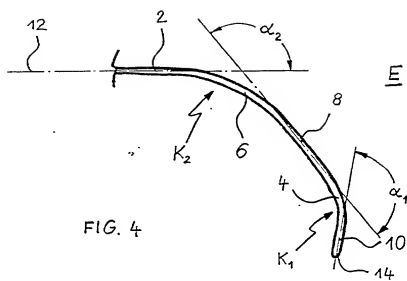


FIG. 4

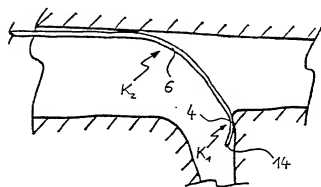


FIG. 5

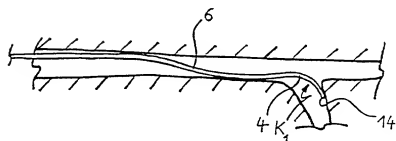


FIG. 6

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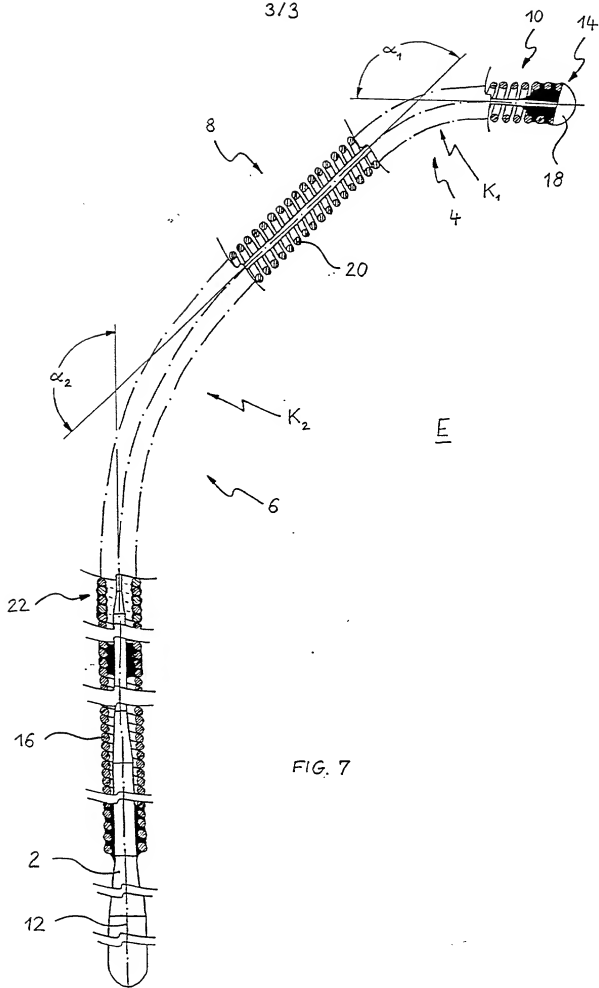


FIG. 7

COMBINED DECLARATION/POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled GUIDING AID, the specification of which (check one):

_____ is attached hereto

☒ was filed on March 7, 2002
as U.S. Application
Serial No. 10/070,939

_____ and was amended on (if
applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefit(s) under Title 35, United States Code §119 (a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Prior Foreign Application(s)

Number	:	99117818.7
Country	:	Europe
Day/Month/Year Filed	:	9 September 1999
Priority (yes/no)	:	yes

Number	:	
Country	:	
Day/Month/Year Filed	:	
Priority (yes/no)	:	

Provisional Application No. :
Filing Date :

Provisional Application No. :
Filing Date :

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international applications designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 and that which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No. : PCT/EP00/07739
Filing Date : 9 August 2000
Status (patented, pending, abandoned) :

Application Serial No. :
Filing Date :
Status (patented, pending, abandoned) :

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

17 David M. Crompton, Reg. No. 36,772;
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon, I further declare that I understand the content of this declaration.

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Residence: Winterthur, Switzerland

Citizenship: Switzerland

Post Office Address: Hegfeldstrasse 9, CH-8404 Winterthur, Switzerland

Inventor's Signature Michael Schwager

Date 25.03.2002

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claims patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

[42 FR 5593, Jan. 28, 1997; paras. (d) & (e) – (i), 47 FR 21751, May 19, 1982, effective July 1, 1982; para. (c), 48 FR 2710, Jan. 20, 1983, effective Feb. 27, 1983; paras. (b) and (j), 49 FR 554, Jan. 4, 1984, effective Apr. 1, 1984; paras. (d) and (h), 50 FR 5171, Feb. 6, 1985, effective Mar. 8, 1985; para. (e), 53 FR 47808, Nov. 28, 1988, effective Jan. 1, 1989; 57 FR 2021, Jan. 17, 1992, effective Mar. 16, 1992; para. (e) added, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000]